

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

34-16

5/27/16

PREScribed TREATMENT TO DESTROY TRICHINAE IN PORK, AND PRODUCTS CONTAINING PORK, AS REQUIRED BY 9 CFR 318.10

I. PURPOSE

This notice reissues the content of FSIS Notice 14-15 in its entirety. This notice provides instructions to IPP regarding how to verify that establishments address trichinae during the production of products specified in [9 CFR 318.10\(b\)](#), *Prescribed Treatment of Pork and Products Containing Pork to Destroy Trichinae*. The instructions in this notice are consistent with FSIS's thinking presented in the 2001 proposed rule on Ready-to-Eat (RTE) products, including FSIS's position in that proposed rule that if the establishment identifies *trichinae* as a hazard reasonably likely to occur, the establishment would have to ensure that the process used effectively eliminates the hazard ([66 FR](#) 12590, 12608; February 27, 2001).

NOTE: The instructions in this notice apply only to IPP in establishments producing those products listed in [9 CFR 318.10\(b\)](#) and not to pork carcasses during slaughter or to products that are rendered free of trichinae as a result of being fully cooked during production.

II. BACKGROUND

A. Section 318.10(b) of 9 CFR requires that certain pork products be treated to destroy trichinae. Examples of such products include mixtures of pork with other meats and poultry; bacon wrapped products; breaded pork; raw marinated pork in dark sauces; colored pork; cured pork; and cured and smoked pork. In these products and in other pork products requiring treatment for trichinae, one or more processing steps make it difficult for the consumer to visually determine whether the product has been fully cooked, such as encasing the raw pork or coloring the raw pork.

B. The regulations provide that other pork products, such as uncured pork products (e.g., pork cuts, pork sausage, or bacon), are not required to be treated to destroy trichinae because they are customarily well cooked at home or elsewhere before being served.

C. Many pork products and other products containing pork are treated for trichinae as part of their processing at the federally inspected establishment in a way that results in their attaining one of the time and temperature combinations prescribed in [9 CFR 318.10\(c\)\(1\)](#).

D. Additional processing methods other than those prescribed in [9 CFR 318.10\(c\)](#) may be approved by the Agency provided that the specific method is reviewed and accepted in accordance with in [9 CFR 318.10\(c\)\(4\)](#).

NOTE: These additional or alternative procedures are those that an establishment will use in place of certain provisions of the regulations (e.g., regulatory requirements are waived by FSIS). In lieu of each

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regulation, or provision of a regulation, waived, the establishment will need to use certain relevant alternative procedures.

E. In accordance with the requirements in [9 CFR 424.21\(a\)\(3\)\(iii\)](#), poultry products containing pork muscle tissue must be treated to destroy any possible live trichinae using one of the treatments provided in regulations in [9 CFR 318.10\(c\)](#).

F. [9 CFR 318.10\(a\)\(2\)](#) provides that pork from carcasses or parts that have been found free of trichinae using the test methods specified in [9 CFR 318.10\(e\)](#) or [9 CFR 318.10\(f\)](#) are not required to be treated for the destruction of trichinae.

G. As FSIS stated in the 2001 proposed rule, under the Hazard Analysis and Critical Control Point (HACCP) regulations and changes, certification of pork products may not always be required. IPP need to be aware that establishments may determine through their hazard analysis that trichinae is not a hazard reasonably likely to occur (NRLTO). IPP are also to be aware that to make this determination, establishments will need to have supporting documentation to justify that decision ([9 CFR 417.5\(a\)](#)). An example of a situation in which trichinae is not a hazard that is reasonably likely to occur is when an establishment has documentation that the pork it uses has been certified free of trichinae.

III. IPP RESPONSIBILITIES

A. IPP in establishments that produce pork, and products containing pork (i.e., products identified in [9 CFR 318.10\(b\)](#) and [9 CFR 424.21\(a\)\(3\)\(iii\)](#)) that are subject to the requirements of [9 CFR 318.10](#), are to notify establishment management of this notice at the next weekly meeting.

B. Using the appropriate HACCP verification task for the product being produced, IPP are to review the hazard analysis for those products identified in [9 CFR 318.10\(b\)](#) and for poultry products containing pork as required by [9 CFR 424.21\(a\)\(3\)\(iii\)](#) and determine whether trichinae has been considered.

NOTE: IPP can review the hazard analysis during the performance of either a routine or directed HACCP verification task in accordance with the instructions in [FSIS Directive 5000.1, Verifying an Establishments Food Safety System](#), or when conducting the HAV task as described in [FSIS Directive 5000.6, Performance of the Hazard Analysis Verification \(HAV\) Task](#).

1. If trichinae was considered in the establishment's hazard analysis and determined not to be reasonably likely to occur, IPP are to:
 - a. Review the decision made;
 - b. Determine whether supporting documentation is on file to comply with [9 CFR 417.5 \(a\)\(1\)](#), and whether that documentation supports the decision made in the hazard analysis; and

NOTE: If IPP have questions regarding the adequacy of the support, they are to seek guidance from their immediate supervisor or an Enforcement, Investigation, and Analysis Officer (EIAO) to determine whether there is a basis to question the adequacy of the support and of the hazard analysis.

- c. During the performance of a General Labeling task, determine whether the establishment has elected to use special labeling in lieu of certified pork (i.e., pork treated in accordance with [9 CFR 318.10\(c\)](#)).
2. If trichinae was considered in an establishment's hazard analysis, and the establishment determined that it is reasonably likely to occur, IPP are to verify that the establishment is implementing any of the procedures identified in [9 CFR 318.10\(c\)](#) to prevent, eliminate, or reduce the identified hazard to an acceptable level.

NOTE: In accordance with [9 CFR 318.10\(c\)\(4\)](#), establishments can elect to develop alternative trichinae control procedures (e.g., High Pressure Pasteurization (HPP)). For information regarding alternative processing methods, refer to [9 CFR 318.10\(c\)\(4\)](#). Establishments may refer to the [Guidance Procedures for Notification and Protocol Submission of New Technology](#) or contact the Risk, Innovations, and Management Staff (RIMS) directly at:

United States Department of Agriculture
Food Safety and Inspection Service
Risk, Innovations, and Management Staff
Patriots Plaza III, Cubicle 8-163A
1400 Independence Ave., SW.: STOP 3782
Washington, DC 20250-3700
Tel: (301) 504-0884
Fax: (301) 245-4793

3. If trichinae was not considered in an establishment's hazard analysis, IPP are to conduct the "Other Inspection Requirements" task in order to verify that the establishment:
 - a. Uses pork that has previously been refrigerated, heated, or cured according to the trichinae treatment criteria in [9 CFR 318.10\(c\)](#); or
 - b. Implements any of the procedures identified in [9 CFR 318.10\(c\)](#) to address trichinae in products that have not previously been treated.
4. If IPP determine that the establishment has failed to meet any of the criteria in section III, 1 – 3 above, IPP are to initiate a regulatory control action in accordance with [9 CFR 500.2](#) and document the noncompliance with 9 CFR 318.10(c) by following the instructions in [FSIS Directive 5000.1](#).

IV. SPECIAL LABELING REQUIRED IN LIEU OF CERTIFIED PORK

NOTE: The labeling verification tasks discussed in this section of this Directive are specific to products addressed in [9 CFR 318.10](#) and [424.21\(a\)\(3\)\(iii\)](#) in relation to the destruction of trichinae.

A. IPP are to be aware that if, instead of using certified pork, the establishment places a statement such as "Cook thoroughly" on its label, the label may be generically approved in accordance with 9 CFR 412.2, unless the label is in one of the four specific categories in 9 CFR 412.1 (labels for temporary approval; labels with deviations for export only; labels for religious exempt products; and labels with special statements or claims). In order to ensure that, in accordance with 9 CFR 317.8(a), the final labels are not false or misleading, IPP are to verify that the labels approved generically in accordance with 9 CFR 412.2 contain the information in paragraph B below.

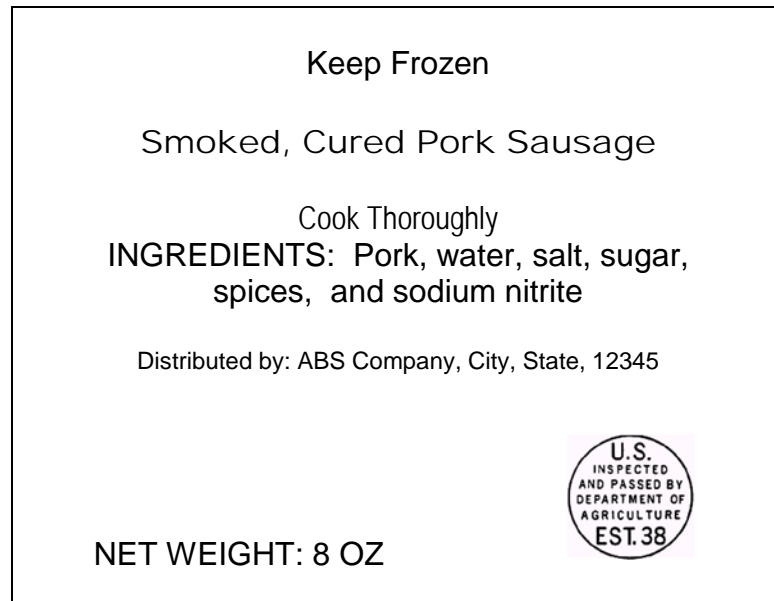
B. If the establishment is using special labeling in lieu of certified pork, IPP are to use the General Labeling task to verify that the official establishment maintains a copy of all labels used in accordance with parts [9 CFR 320.1\(a\)\(11\)](#) and [381.175\(b\)\(6\)](#), and that the following information is present on the immediate container:

1. A prominent statement on the principal display panel that the product is not ready to eat, for example, "Cook Thoroughly," "Ready to Cook;"
2. Cooking instructions that result in a ready to eat product (e.g., Cook to an internal temperature of 160 degrees Fahrenheit); and

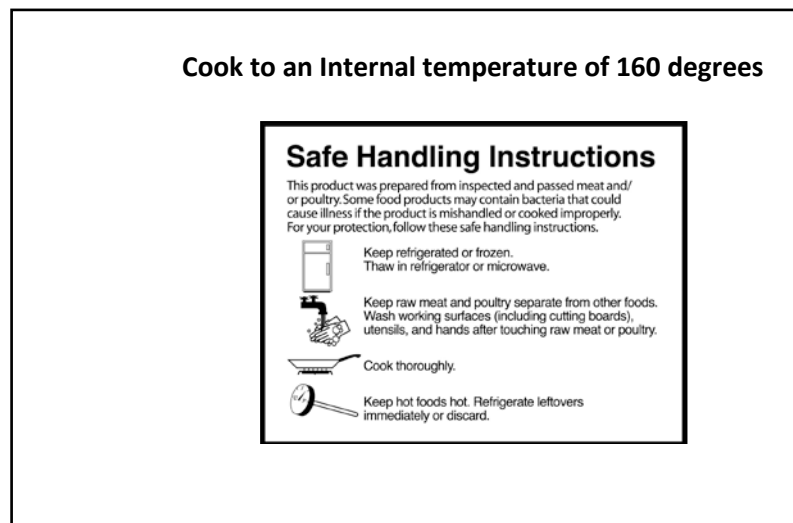
NOTE: If cooking instructions per B.2 above appear on the principal display panel, then the prominent statement identified in B.1 above can be omitted

3. Safe handling instructions if the product is raw, or if the meat or poultry ingredient is not ready to eat.

C. An example label, along with Safe Handling Instructions, appears below:



(Principal Display Panel)



(Back Panel)

NOTE: The information in the safe handling instructions cannot be used in lieu of the prominent statement described in Section B.1 or the cooking directions in Section B.2 above. These features need to be separate and distinct from the safe handling instructions.

V. QUESTIONS

Refer HACCP questions to the Policy Development Staff (PDS) and labeling questions to the Labeling and Program Delivery Staff (LPDS) through [askFSIS](#). PDS and LPDS can also be reached by telephone at 1-800-233-3935 (For PDS- press 6; for LPDS- press 4).

When submitting a question through [askFSIS](#), use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Notice 34-16**

Question Field: Enter your question with as much detail as possible.

For **HACCP questions**:

Product Field: Select **PDD General** from the drop-down menu

Category Field: Select **HACCP** from the drop-down menu

Policy Arena: Select **Domestic (U.S.) only** from the drop-down menu

For **Labeling questions**:

Product Field: Select **Labeling** from the drop-down menu.

Category Field: Select **Labeling Regulations, Policies and Claims** from the drop-down menu

Policy Arena: Select **Domestic (U.S.) only** from the drop-down menu

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



Assistant Administrator
Office of Policy and Program Development